K02 1279
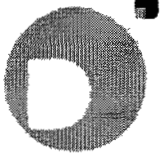
Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

July 19, 2002

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software

COMMON NAME:

Patient Monitor

CLASSIFICATION NAME:

The following Class III classification appears applicable:

DSI	Arrhythmia detector & alarm	870.1025
MLD	Monitor ST-segment & alarm	870.1025

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL
EQUIVALENCE IS MADE as required by 807.92(a)(3)

The new Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software is
substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-
Ohmeda AS/3™ Anesthesia Monitor with S-ANE99(A)/L-ARK99(A) software (K000815).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The intended use and indications for use for the modified device, Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software are similar to the predicate Datex-Ohmeda AS/3™ Anesthesia Monitor with S-ANE99(A)/L-ARK99(A) software (K000815).

There has been no change to the fundamental scientific technology from the predicate.

The device description of the Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software is as follows:

The S/5™ Anesthesia Monitor is a patient monitor, which displays the measurement of patient physiological parameters in the hospital setting.
The measurement of patient physiological parameters is accomplished by specialized measurement modules which, when plugged into the frame, allow the modules to communicate with the monitor. The care giver can select from a variety of available measurements (parameters) and apply those parameters that are best suited to patient care. Modules perform the functions of parameter measurement and minor data processing. The S/5™ Anesthesia Monitor displays parameters on screen, signals alarms and performs advanced data processing.

There are two software options available for the S/5™ Anesthesia Monitor:
L-ANE02 and L-ANE02A.

L-ANE02A is equipped with extended arrhythmia analysis capability. Other than arrhythmia analysis capabilities, this software option is identical to L-ANE02.

The modifications to the device are:
1. Improved Central Processing Unit Board, B-CPU5, with increased memory capability.
2. Improved Universal Peripheral Interface Board, B-UPI4NET, which is a combination of the previous B-UPI and B-NET boards.
3. Rotating of the "ComWheel" now scrolls through different trend pages.
4. Technical alarms such as "SpO2 probe off", "Leads off" (ECG), and "Px No transducer" (InvBP) transferred to the Central Station.
5. Changed to include support for alarm silencing and alarm limits adjustment from Central Station.
6. The alarm priority of "X module removed" message has been increased from note level to yellow level.
7. Software can additionally send request for recording to Central Station.
8. Snapshot printing speed 25 mm/s has been added.
9. Support for M-BIS (Bispectral Index) module has been added. M-BIS is the subject of a separate 510(k) premarket notification
10. Support for the M-miniC (CO2 module) module has been added. The Mini CO2 module M-miniC is the subject of a separate 510(k) premarket notification.
11. Support for the N-DIS external device interfacing modules for interfacing of the following device categories: ventilators/anesthesia machines, stand-alone monitors, blood gas analyzers and heart-lung machines has been added. The N-DIS modules is the subject of a separate 510(k) premarket notification

12.   Uses an arrhythmia analysis version which has an improved vfib algorithm compared to arrhythmia analysis version submitted in the predicate 510(k).

13.   Patient name menu items have been activated also when Anesthesia Record Keeper (ARK) is selected from the monitor menu to be "OFF".

The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A uses several types of plug-in measurement modules. Modules are the subject of separate 510(k)'s and are not part of this notification. The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A is typically furnished with a module that measures ECG, invasive and non-invasive blood pressures, pulse oximetry and temperature. Modules are placed in the S/5™ monitor frame and are automatically recognized by the monitor. The patient cables are connected to the module plug in jacks and then monitoring can begin. The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A can display measurements in the form of numeric values, traces and trends. Audible and visual alarms are used to indicate patient status. The priority profile of an alarm depends on the parameter. The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A is operated by a keyboard. Typically pressing a key results in a pop up menu appearing on the screen. Selections can then be made easily from the menu using a unique ergonomically designed pointing device on the keyboard called a ComWheel™. The software L-ANE02 and L-ANE02A perform some module related tasks like arrhythmia analysis, ST–values calculation, heart rate calculation, impedance and respiration rate calculation, energy expenditure calculation, EEG spectrum analysis and evoked potential response averaging. All the module communication is also handled in the main software. The software L-ANE02 and L-ANE02A also include the option of creating patient care documentation. The trend information is automatically transferred to the anesthetic record, and the related events and medication can be easily entered with the same user interface as the monitor itself. There are various optional types of keyboards, some are like standard keyboards and another is a hand-held Remote controller (REMCO) which is still directly connected to the S/5™ Anesthesia Monitor via a long cord but provides more flexibility in controlling the monitor while the doctor or nurse is handling other patient care needs. Using the Anesthesia Record Keeper software, patient related care events are documented using the keyboard. To facilitate quick access to menus, a bar code reader is also available. The S/5™ Anesthesia Monitor can be in a stand-alone or networked configuration. If networked, measurements are sent to the network for central station or monitor-to-monitor viewing. Trends as well as the patient care documentation can be sent via a network to a central computer for archiving.

INTENDED USE as required by 807.92(a)(5)

The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A is intended for multiparameter patient monitoring with optional patient care documentation.

Indications for use:

The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Bispectral index (BIS), and neurophysiological status of all hospital patients.

The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software when using BIS is for monitoring the state of the brain by data acquisition and processing of electroencephalograph signals and may be used as an aid in monitoring the effects of certain anesthetic agents*.
(*Gan TJ, Glass P, Windsor A, Payne F, Rosow C, Sebel P, Manberg P. Bispectral Index Monitoring Allows Faster Emergence and Improved Recovery from Propofol, Alfentanil and Nitrous Oxide Anesthesia. Anesthesiology, October 1997; (4) 87:808-15.)

The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software is also indicated for documenting patient care related information.

The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software is substantially equivalent to the the Datex-Ohmeda AS/3™ Anesthesia Monitor with S-ANE99(A)/L-ARK99(A) software (K000815).

The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Bispectral index (BIS), and neurophysiological status of all hospital patients. The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software when using BIS is for monitoring the state of the brain by data acquisition and processing of electroencephalograph signals and may be used as an aid in monitoring the effects of certain anesthetic agents*. (*Gan TJ, Glass P, Windsor A, Payne F, Rosow C, Sebel P, Manberg P. Bispectral Index Monitoring Allows Faster Emergence and Improved Recovery from Propofol, Alfentanil and Nitrous Oxide Anesthesia. Anesthesiology, October 1997; (4) 87:808-15.) The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software is also indicated for documenting patient care related information. The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software is indicated for use by qualified medical personnel only.

There are two software options available for the S/5™ Anesthesia Monitor: L-ANE02 and L-ANE02A (collectively referred to as L-ANE02(A)). (Note: L- refers to software license). Only one software can be used at any given time in the monitor. The software is preloaded in the factory.

The new device with different software options, S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A, is compared to predicates as outlined below.
The basic model of the monitor is the S/5™ Anesthesia Monitor with L-ANE02, which is a new revision of the predicate devices, AS/3™ Anesthesia Monitor with S-ANE99(A)/L-ARK99(A) (K000815).

The S/5™ Anesthesia Monitor with L-ANE02 may be equipped with extended bedside arrhythmia analysis capability and in this case the monitor is called S/5™ Anesthesia Monitor with L-ANE02A. The arrhythmia analysis functionality of the S/5™ Anesthesia Monitor with L-ANE02A is substantially equivalent to the functionality of the predicate device AS/3™ Anesthesia Monitor with L-ARK99A.

The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A is a modular multiparameter patient monitor providing connections to measurement modules. The general construction, indications for use and intended use of the S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A are similar as compared to the predicate AS/3™ Anesthesia Monitor with S-ANE99(A)/L-ARK99(A) (K000815).

Based on the above and a detailed analysis in the 510(k) documentation it is evident that the main features and indications for use of the S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software is substantially equivalent to the predicate AS/3™ Anesthesia Monitor with S-ANE99(A)/L-ARK99(A) software (K000815).

<u>SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by</u>
<u>807.92(b)(1)(3)</u>

The Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- IEC 60601-1:1988+ Amdt.:1:1991 + Amdt. 2:1995
- EN 60601-1: 1990 + A1:1993+A2:1995+A13:1996
- CAN/CSA-C22.2 No.601.1-M90 +S1:1994+Amdt. 2:1998
- IEC 60601-2-27:1994/EN 60601-2-27:1994
- IEC 60601-2-30:1995/EN 60601-2-30:1995
- IEC 60601-2-34:1994/EN 60601-2-34:1994
- IEC 60601-2-40:1998
- IEC 60601-1-2(1993)/EN 60601-1-2
- IEC 60601-1-4: 1996+Amdt. 1:1999/EN 60601-1-4
- ISO 9918:1993/EN 864:1996
- ISO 9919:1992/EN865:1997
- ISO 7767:1997/EN12598:1999
- ISO 11196:1995 + Corr. 1:1997/EN ISO11196:1997
- IEC 601-2-10:1987/HD 395.2.10:1988 + Am.1:2000
- IEC 60601-2-26:1994/EN60601-2-26
- IEC 60068-2
- UL 2601-1:1997
- ANSI/AAMI ES-1:1993
- ANSI/AAMI EC57:1998
- FDA 21 CFR 898.12

<u>Conclusion:</u>
The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software as compared to the predicate device.

NOV 2 7 2002

Mr. Joel C. Kent
Datex-Ohmeda
86 Pilgrim Road
Needham, Massachusetts 02492

Re: K021279
        Trade/Device Name:Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE02 and
        L-ANE02A software
        Regulation Number: 870.1025
        Regulation Name: Arrhythmia Detector and Alarm
        Regulatory Class: III
        Product Code: MHX and GWQ
        Dated: November 7, 2002
        Received: November 14, 2002

Dear Mr. Kent:

This letter corrects our substantially equivalent letter of July 19, 2002 regarding the
Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software.

We have reviewed your Section 510(k) premarket notification of intent to market the device
referenced above and have determined the device is substantially equivalent [(for the
indications for use stated in the enclosure)] to legally marketed predicate devices marketed
in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device
Amendments or to devices that have been reclassified in accordance with the provisions of
the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket
approval (PMA). You may, therefore, market the device, subject to the general controls
provisions of the Act. The general controls provisions of the Act include requirements for
annual registration, listing of devices, good manufacturing practice, labeling, and
prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III
(PMA), it may be subject to additional controls. Existing major regulations affecting your
device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898.
In addition, FDA may publish further announcements concerning your device in the Federal
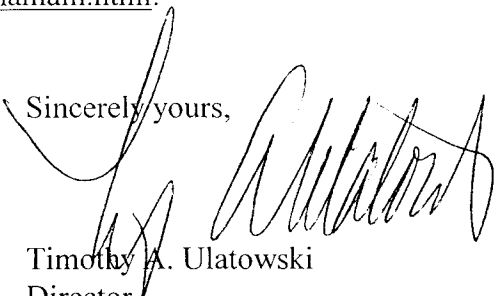Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
    Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
    Radiological Health

Enclosure

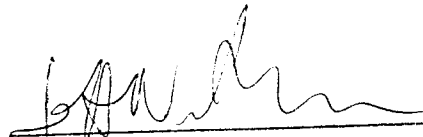510(k) Number (if known): _____ K021279 _____

Device Name: S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software

The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Bispectral index (BIS), and neurophysiological status of all hospital patients.

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The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software is also indicated for documenting patient care related information.

The S/5™ Anesthesia Monitor with L-ANE02 and L-ANE02A software is indicated for use by qualified medical personnel only.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K021279

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓   OR   Over-The-Counter Use _____
(Per 21 CFR 801.109)
                                        (Optional Format 1-2-96)